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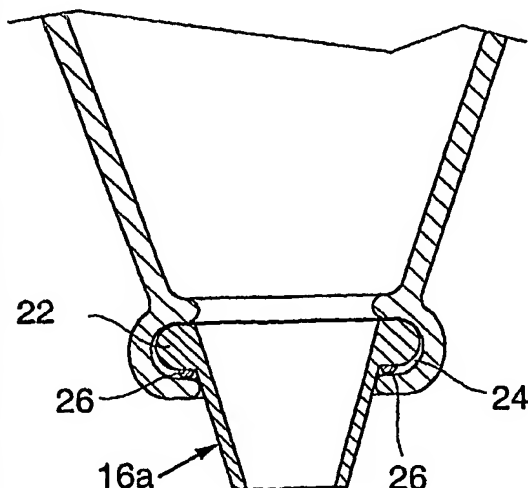
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(54) Title: METHOD AND APPARATUS FOR MODIFYING THE EXIT ORIFICE OF A SATIATION POUCH



(57) Abstract: A prosthetic device is described that is positionable within the gastro-esophageal junction region of a patient. The prosthetic device includes a proximal opening and a distal orifice that is adjustable in size prior to and/or following implantation. During use, the prosthetic device is attached to tissue of the gastro-esophageal junction region of the patient, with the device positioned such that food ingested by the patient passes from the esophagus through the proximal opening into the interior of the prosthetic device, and eventually exits the prosthetic device via the distal opening.

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**METHOD AND APPARATUS FOR MODIFYING
THE EXIT ORIFICE OF A SATIATION POUCH**

5 **Field of the Invention**

The present invention relates generally to the field of devices and methods for achieving weight loss in humans, and specifically to the use of devices implantable within the human stomach for controlling feelings of hunger and/or limiting food intake.

10 **Background of the Invention**

An anatomical view of a human stomach S and associated features is shown in Fig. 1A. The esophagus E delivers food from the mouth to the proximal portion of the stomach S. The z-line or gastro-esophageal junction Z is the irregularly-shaped border between the thin tissue of the esophagus and the thicker tissue of the stomach wall. The gastro-esophageal junction region G is the region encompassing the distal portion of the esophagus E, the z-line, and the proximal portion of the stomach S.

Stomach S includes a fundus F at its proximal end and an antrum A at its distal end. Antrum A feeds into the pylorus P which attaches to the duodenum D, the proximal region of the small intestine. Within the pylorus P is a sphincter that prevents backflow of food from the duodenum D into the stomach. The middle region of the small intestine, positioned distally of the duodenum D, is the jejunum J.

Prosthetic devices for use in controlling obesity are shown and described in U.S. Application No. 09/940,110, filed August 27, 2001 and U.S. Application No. 10/118,289 filed April 8, 2002, and U.S. Provisional Application No. 60/379,306 filed May 10, 2002. These applications are owned by the assignee of the present application, and the disclosures of these applications are incorporated herein by reference. Certain forms of these devices involve positioning a prosthetic pouch in the proximal stomach as shown in Fig. 1B. The pouch 2 includes a proximal opening 4 and a smaller distal opening 6 and forms a small reservoir that collects masticated food from the esophagus – thereby limiting the amount of food that can be consumed at one time. As the pouch fills with food, it may distend, imparting pressure against the upper stomach and lower esophageal sphincter causing the patient to experience sensations of fullness. The pouch may

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additionally or alternatively act as a restrictor, limiting the amount of food intake. The pouch is fixed in place using clips, sutures, suitable adhesives or other means 8 at anchor points around the perimeter of the proximal opening 4.

The amount by which food intake should be restricted varies between patients. It
5 may thus be desirable to increase or decrease the amount of food a patient can ingest by selecting an appropriate diameter for the pouch's distal orifice. A smaller orifice will cause food to descend from the pouch into the stomach more slowly than will a larger orifice, and will thus limit the amount of food the patient can consume at one time.

Satiation pouches may be available in multiple distal orifice sizes (and/or multiple
10 pouch sizes) to permit the physician to select a size that is appropriate for the targeted food intake for the patient. Alternatively, satiation pouches may be configured to allow the size of the pouch's distal opening to be increased or decreased. This enables a physician implanting such a device to set the distal opening to a size appropriate for a patient. In some cases, it will also allow the physician to make adjustments to the distal
15 opening after it has been implanted. For example, if the patient is not losing weight at a desired rate, the physician might reduce the size of the distal opening – so that food will empty more slowly from the pouch into the stomach. The physician might alternatively increase the size of the distal opening if necessary if weight loss is occurring too rapidly – or if the patient is suffering from nausea and requires that the pouch be opened to allow
20 the patient to vomit more easily. The present application describes various satiation pouches which have adjustable distal orifice sizes and which thereby provide the physician with enhanced control over the degree of food consumed by the patient at one time.

25 Summary of the Invention

The present invention includes a prosthetic device positionable within the gastro-esophageal junction region of a patient, wherein the prosthetic device includes a proximal opening and a distal orifice that is adjustable in size prior to and/or following
implantation. During use, the prosthetic device is attached to tissue of the gastro-
30 esophageal junction region of the patient, with the device positioned such that food ingested by the patient passes from the esophagus through the proximal opening into the

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interior of the prosthetic device, and eventually exits the prosthetic device via the distal opening.

Brief Description of the Drawings

5 Fig. 1A is a schematic illustration of a human stomach and a portion of the small intestine.

 Fig. 1B is a perspective view of a satiation pouch shown positioned in the stomach.

 Fig. 2A is a perspective view of a first embodiment of a satiation pouch including
10 a set of distal inserts each having a different distal orifice size.

 Fig. 2B is a perspective view of the satiation pouch of Fig. 2A having one of the distal inserts connected to the pouch.

 Fig. 3A is a cross-sectional side view of the pouch of Fig. 2A.

 Fig. 3B is a cross-sectional side view of one of the distal inserts of Fig. 2A.

15 Fig. 3C is a cross-sectional side view of the distal portion of the pouch of Fig. 3A, with the insert of Fig. 3B assembled with the pouch.

 Fig. 4A is a perspective view of a second embodiment of a satiation pouch, shown together with devices for increasing and reducing the orifice diameter.

 Fig. 4B is a perspective view of the pouch of Fig. 4A showing the expander in use
20 to increase the orifice size.

 Fig. 4C is a perspective view of the pouch of Fig. 4A showing a reduction tool in use to decrease the orifice size.

 Fig. 5A is a perspective view of a third embodiment of a satiation device.

 Fig. 5B is a perspective view of a fourth embodiment of a satiation device

25 Fig. 6A is a front elevation view of a fifth embodiment of satiation pouch having an alternative form of adjustable distal opening.

 Fig. 6B is a top plan view of the adjustable restrictor ring of the pouch of Fig. 6A.

 Fig. 7 is a side elevation view of a sixth embodiment of a satiation pouch having yet another form of adjustable distal opening, and a tool useable for adjusting the distal
30 opening.

 Figs. 8A and 8B are side elevation views showing the distal end of the tool shown in Fig. 7 in the retracted and expanding positions, respectively.

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Figs. 9A and 9B are top plan views of the adjustable restrictor ring of the pouch of Fig. 33, showing the ring in expanded and contracted positions.

Fig. 10 is a perspective view of a seventh embodiment of a satiation device together with a tool used to vary the diameter of the distal orifice.

5 Fig. 11 is a perspective view of an eighth embodiment of a satiation device.

Figs. 12A and 12B are perspective views of a ninth embodiment of a satiation device.

Fig. 13 is a perspective view of a tenth embodiment of a satiation device.

10 Figs. 14A and 14B are bottom elevation views of an eleventh embodiment of a satiation device, showing the distal orifice in a reduced-diameter configuration and in an expanded-diameter configuration, respectively.

Figs. 15A and 15B are perspective views of twelfth embodiment of a satiation device. Fig. 15B shows the pouch following reduction of the size of the distal orifice.

15 Figs. 16 through 18 are side perspective views showing the distal orifice of a satiation pouch being expanded using a variety of cutting tools.

Fig. 19A is a side elevation view of a cutting tool for expanding the distal orifice size of a satiation pouch. Fig. 19B is a detailed view of the region within the circle 19B-19B in Fig. 19A.

20 Fig. 20A is a cross-sectional side perspective view of a satiation pouch having an adjustable orifice size.

Fig. 20B is a partially cutaway side perspective view of the pouch of Fig. 20A illustrating adjustment of the orifice size.

Detailed Description of the Drawings

25 The drawings show a number of embodiments of satiation pouches having features that permit the size of the distal or exit orifice to be altered before and/or following implantation. The term "exit orifice" will be used to describe the smallest orifice through which food flows from the interior of the pouch towards the stomach. In referring to the step of modifying the size of the distal orifice or exit orifice of the device,
30 the term "size" will be used to refer to the dimensions that, when modified, will change the rate at which ingested food flows through the orifice.

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For the purposes of this application, the term "satiation devices" or "satiation pouches" will be used to mean prosthetic devices including pouches intended to induce weight loss in one or more of a variety of ways. These include, but are not limited to, physically restricting the amount of food that can be consumed, and/or imparting pressure
5 against portions of the body (e.g. stomach, esophagus, esophageal sphincter, etc) causing the patient to experience sensations of fullness, and/or affecting levels of hormones or other substances in the body that control or affect feelings of hunger, and/or affecting the amount of ingested food absorbed by the body.

The pouch of each described embodiment may be formed of a flexible material
10 that will prevent passage of food through the sides of the pouch. Examples of such materials include, but are not limited to polyesters (e.g. Dacron® polyester), ePTFE fabric (e.g. GoreTex® fabric or others), a polyurethane such as ChronoFlex® polyurethane, nylon fabrics, silicone, other polymeric materials, and bio-absorbable materials (e.g. PLLA, PGA, PCL, poly-amhydride etc). The material may be a composite
15 of compliant, semi-compliant and/or non-compliant materials that give different regions of the pouch different degrees of compliance so as to allow/limit expansion of the pouch in various locations. For example, it may be desirable to provide the pouch with a fairly elastic exit port to as to prevent occlusion in the event a large piece of food is ingested and/or to control the exit pressure of food from the pouch, whereas the proximal end of
20 the pouch may be stiffer to prevent bulging. Varying degrees of compliance may also be built into the pouch by varying the cross-sectional thickness in different regions of the pouch. The material may be coated with a lubricious, bio-compatible, chemically inert material, such as paraflex, to reduce friction on the base material's surface which will help prevent sticking and food build up on the device.

25 The flexible pouch material may be reinforced with, constructed of, or supported by supporting members, such as a soft mesh, a cage structure, ribs, rings etc. The supporting members may be formed of stainless steel, polymer, shape memory materials such as nitinol, shape memory alloys, or shape memory polymers, or thickened regions of material. The pouch may be constructed so as to be self-expanding, such that the pouch
30 springs radially open into an expanded condition upon ejection from a deployment device or catheter.

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Implantation of the described devices is preferably performed endoscopically, by passing the devices through the esophagus, preferably under endoscopic visualization. Alternatively, the devices may be implanted using surgical or laparoscopic procedures.

During implantation the pouch is secured at the gastro-esophageal junction region
5 G using sutures, clips, adhesives, stents or stent-like structures, or other suitable means. One suture attachment device found useful for applying sutures between the pouch and tissue is the "Sew-Right" suturing device available from LSI Solutions of Victor, New York,. Although the pouch may be secured to the esophageal tissue, it is more preferable to apply sutures/clips below the Z-line to allow for attachment to the thicker tissue of the
10 stomach wall.

Each of the described pouches includes a proximal opening and a distal exit port (see openings 4 and 6, respectively, of Fig. 1B). Because of its small volume (which may be on the order of approximately 2 cc-300cc in volume, but is preferably in the range of 10-30 cc), the pouch functions to limit the amount of food that can be consumed at one
15 time. Over time the food within this reservoir descends into the stomach through the exit port.

First Embodiment

A first embodiment of a satiation pouch having a variable-size orifice is shown in
20 Figs. 2A through 3C. Pouch 10 includes a proximal opening 12, a distal opening 14, and a passage extending between the proximal and distal openings. Inserts 16a, 16b are provided for attachment to the pouch 10. Preferably two or more such inserts 16a, 16b are provided, each with a different sized distal orifice 18a, 18b. For example, a collection of inserts may be provided with distal orifices each having different diameters in the
25 range of 6 – 14 mm (for a circular orifice). Each insert includes a proximal opening 20 surrounded by a rim 22. Rim 22 is proportioned to seat within a recess 24 (Fig. 3A) formed in the interior wall of the pouch 10 when the insert 16a is placed inside the pouch with the orifice 18a extending in a distal direction. See Figs. 2B and 3C. The rim 22 may be structurally reinforced using a ring formed of nitinol, stainless steel, thick silicone, etc
30 if necessary to insure a snug fit between the insert and pouch.

Prior to implantation of the pouch 10, the physician selects an insert having a diameter that is appropriate for the patient. S/he does so by choosing an insert having a

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distal orifice size that will cause food to descend from the stomach at a desired rate.

Next, the physician passes the insert through the proximal opening 12 of the pouch 10 and presses rim 22 of the insert into engagement with recess 24 of pouch. It may be necessary to dilate the distal opening 14 of the pouch while rim 22 is being seated within the recess 24.

The distal face of rim 22 may include bumps 26 as shown in Fig. 3B. When the pouch and insert are assembled, these bumps 26 urge the proximal face of the rim against the upper surface of the recess (Fig. 3C), so as to prevent accumulation of ingested food in spaces that would otherwise be left between them. The connection between the pouch and insert may be reinforced if desired using sutures or other means. After the pouch and insert are assembled, the pouch is implanted at the gastro-esophageal junction region.

It should be noted that assembly of the pouch and insert may alternatively be carried out after the pouch has been implanted. Holes 28 (Fig. 3B) facilitate grasping of the insert using forceps or other tools during assembly.

If the physician determines at a later time (for example, after hours, days, weeks, months or even years) that an insert having a different orifice size would be more appropriate for the particular stage of the patient's treatment, the insert 16a may be removed from the pouch 10 (such as by grasping it using forceps and withdrawing it through the proximal opening 12) and replaced with another pouch.

Although the pouch 10 is shown as having proximal opening 12 that is larger than the distal opening 14, the pouch may be provided with a larger distal opening 14, including one that is equal to or greater in size than the proximal opening. Such an embodiment might be used, for example, in a patient for whom it would be desirable to allow the patient to heal from the initial implantation and/or adjust to the presence of the implanted pouch before the exit orifice is reduced. After an appropriate healing/adjustment period (for example, at least one day and as long as approximately two weeks in order to allow the suture/anchor attachment points to heal), a separate procedure would be performed to add the insert or other flow restrictive component to the pouch 10, preferably by passing the component down the esophagus towards the stomach. During implantation of the insert or other component, it may be desirable to clear the pouch of any food material that may have accumulated in the recess 24. It should also be noted that if a healing/adjustment period is intended, the pouch design might be modified

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slightly so as to minimize the chance that food material will accumulate within the recess 24.

Another variation on the concept of adding a flow restrictive component after an initial adjustment period involves initially implanting a base device at the gastro-
5 esophageal junction region, where the base device need not be a satiation pouch but is a base to which a pouch will be attached following the healing/adjustment period. For example, the base may take the form of an annular ring or other device that is secured at the gastro-esophageal junction region using sutures, clips, staples etc. The ring may be formed of a variety of materials, including those listed for use to form the pouch. After
10 the healing/adjustment period, a satiation pouch may then be attached to the base using screws, snaps, sutures, clips, staples or other fasteners.

Many variations of the first embodiment are possible and are considered within the scope of applicant's disclosure. For example, the inserts may be replaced with other types of interchangeable components that add a larger or smaller orifice to the pouch. For
15 example, one such component may be similar to the inserts 16a, 16b but attach to the exterior of the pouch rather than being seated in the pouch interior. Also, the inserts or alternative components may be attachable to the pouch using other means such as sutures, clips, adhesives, etc.

20 *Second Embodiment*

Fig. 4A shows a second embodiment of a satiation pouch 30. Pouch 30 includes a distal orifice 32 having a size that may be increased or decreased prior to or following implantation. A ductile ring 34 is located at the distal portion of the pouch, near the distal orifice 32. The ring is preferably formed of a malleable, ductile material (e.g. annealed
25 stainless steel, copper or other metal, or plastic). It may be shaped in a spring configuration as shown, or it may have a stent-like or other type of configuration. Ring 34 may be on the interior or exterior surface of the pouch 30, or embedded within the pouch material.

Pouch 30 is provided with tools for use in increasing and decreasing the diameter
30 of the ring 34 so as to increase/decrease the size of the distal orifice 32. For example, an expansion tool may take the form of a balloon dilator 36 positionable within the pouch and then inflated as shown in Fig. 4B to expand the ring 34. Another example might be

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an expandable basket-type catheter. A reduction tool 38 may have an umbrella-like configuration as shown in Fig. 4A. During use, the operative head 39 of the tool 38 is placed in its closed position and passed through the pouch and out the distal orifice 32. Once outside the distal orifice, the head 39 is expanded, drawn in a proximal direction
5 such that it surrounds the ring 34 (Fig. 4C), and then moved to the closed position to press the ring into a smaller-diameter configuration. Afterwards, the tool 38 is withdrawn from the pouch.

In this and all of the described embodiments, modifications to the exit orifice size may be performed at various different stages in the patient's treatment. For example, if a
10 physician determines following implantation of the pouch (for example, after hours, days, weeks, months or even years) that a prosthesis having a different orifice size would be more appropriate for the particular stage of the patient's treatment, the necessary tools may be passed through the esophagus and used to modify the orifice size. As another example, the pouch may be initially implanted with a large (e.g. as large as, or larger
15 than, the proximal opening) exit orifice. Then, following an adjustment period and/or healing of the sutures/fasteners etc. at the implant site, a second procedure is performed to modify the exit orifice to a desired size.

Figs. 20A and 20B illustrate another pouch in which malleable material may be used to provide adjustability to the exit orifice. Pouch 30a is provided with an exit orifice
20 32a and an adjustment orifice 32b, which share a common wall 33. The pouch 30a is constructed such that expansion of an expansion tool (e.g. balloon dilator 36) within adjustment orifice 32b reduces the size of exit orifice 32a, such as by deforming common wall 33 towards the exit orifice 32a as shown in Fig. 20B. Likewise, use of the expansion tool within exit orifice 32a will deform common wall 33 away from the exit orifice to
25 increase the size of the exit orifice. A portion of the pouch, such as the wall 33 or rings/bands surrounding the distal and adjustment orifices, is preferably formed of a malleable material to allow the exit orifice 32a to retain its adjusted size unless its size is further altered using the expansion tool.

30 *Third and Fourth Embodiments*

A variation on the second embodiment is the third embodiment shown in Fig. 5A. The third embodiment includes a pouch 40 having an annular web 42 at its distal end,

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forming a distal orifice 44. Examples of suitable materials for the webbing 42 include those listed above for use with the pouch. A low yield-strength ring 46 is connected to the exterior perimeter of the webbing. To increase the diameter of the orifice 44, a dilation tool such as dilator 36 of Fig. 4A is passed through the orifice 44 and expanded to
5 expand the ring. The expanded ring draws the webbing radially outwardly, thereby increasing the size of the orifice 44. A reduction tool such as tool 38 of Fig. 4A may be used to compress the ring to a smaller-diameter size and to thereby reduce the diameter of the orifice 44.

The pouch 40a of the fourth embodiment, shown in Fig. 5B, operates in similar
10 fashion to that of the third embodiment, but includes webbing 42a and a ring 46a that extend radially outwardly from the distal orifice 44a.

Fifth and Sixth Embodiments

Referring to Figs. 6A and 6B, a fifth embodiment of a pouch 50 may alternatively
15 be provided with a restrictor ring 52 surrounding the exterior of the pouch - near the distal opening. Ring 52 may be expanded by applying expansive radial forces from within the inner diameter of the ring (e.g. using a dilator as described or by positioning the jaws of a grasper within the funnel and then separating the jaws), or compressed using compressive forces applied to the exterior of the ring (e.g. by positioning the ring between the jaws and
20 then closing them slightly). This expansion/compression may be performed prior to implantation, or after the pouch has been implanted.

Fig. 7 shows a third alternative embodiment of a pouch 60 having an adjustable distal opening. The Fig. 7 embodiment is similar to the Fig. 6A embodiment in that it relies upon expansion/contraction of a restrictor ring 62. Restrictor ring 62 is positioned
25 inside the pouch near the distal opening. A pair of opposed slots 64 are formed in the interior surface of the ring 62. An endoscopically-controllable adjustment tool 66 includes a pair of extendable pins 68 at the distal end of an elongate shaft 70. Actuators 72a,b on the proximal end of the adjustment tool 66 control extension of the pins between the retracted position (Fig. 8A) and the extended position (Fig. 8B). To adjust the
30 diameter of the pouch 60, tool is inserted through the pouch with the pins 68 in the retracted position. Pins 68 are aligned with slots 64 in the ring 62 and are then extended using actuator 72a. As they extend, the pins 68 slide into the slots 64. Next, the user

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rotates the tool 70 about its longitudinal axis, in either the clockwise or counter-clockwise direction. Rotation of the tool expands or contracts the ring, depending on the direction of rotation. After the ring size has been adjusted, the pins 68 are retracted using actuator 72b, and the tool 66 is removed from the pouch 62.

5

Seventh through Ninth Embodiments

An inflation medium such as gas or saline may be used to affect an increase or decrease in the distal orifice size, either before or after the pouch has been implanted. For example, in the seventh embodiment shown in Fig. 10, pouch 80 includes an inflatable
10 annular region 82 adjacent to the distal orifice 84. An endoscopic inflation/deflation tool 86 is passed through the oral cavity and into the pouch to inject and/or withdraw inflation medium using an inflation/deflation needle 88 insertable into an inflation port in the region 82. The region 82 may be an integral portion of the pouch 80, or it may take the form of an inflatable ring 82a as shown on the pouch 80a of the eighth embodiment,
15 which is shown in Figs. 11A and 11B. Fig. 11A shows the ring undergoing expansion, while Fig. 11B shows the ring sufficiently expanded to open (optional) pleats 89 in the pouch 80a.

Pouch 90 of the ninth embodiment (Fig. 12) includes a pair of annular inflation chambers 92, 94 joined by a bi-directional valve 96 such that inflation medium displaced
20 from one chamber passes through valve 96 into the other chamber. If it is desired to increase the diameter of distal orifice 98, a dilation tool (such as tool 36 of Fig. 4A) is positioned within the orifice 98 and expanded, causing inflation medium in the chamber 94 to pass through valve 96 and into chamber 92 – thereby allowing ingested food to flow more freely through orifice 98. To decrease the diameter of distal orifice 98, the dilation
25 tool is dilated against the upper chamber 92, to cause displacement of inflation medium into the lower chamber 94 and thereby to cause chamber 94 to expand radially inwardly to decrease the diameter of orifice 98.

Tenth Embodiment

30 Pouch 100 of the tenth embodiment (Fig. 13) uses a zipper configuration (similar to that found on plastic storage bags) to increase or decrease the size of the distal orifice. A longitudinal cut 102 is provided in the pouch wall. A zipper carriage 104 is slidable in

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a proximal direction along the cut to separate the edges 106a, 106b and to thus increase the size of the distal orifice 108. Movement of the carriage 104 in the distal direction joins the edges 106a, 106b together to decrease the size of the distal orifice 108.

5 ***Eleventh Embodiment***

Figs. 14A and 14B show the distal end of an eleventh embodiment of a pouch 110. The distal end of pouch 110 includes a diaphragm 112 defining distal orifice 114. The diaphragm 112 is similar to the shutter of a camera in the sense that it includes leaves 116 that are rotatable to increase or decrease the distal orifice 114, depending on the direction of rotation. Various mechanisms may be used for rotating the diaphragm, including a manual screw-type actuator engageable by an endoscopic tool passed through the oral cavity and into the pouch, or a microelectromechanical motor activated from an endoscope accessory under direct visualization or activated wirelessly from outside of the patient's body.

15

Twelfth Embodiment

In accordance with a twelfth embodiment of a pouch 120, the pouch 120 includes a drawstring 122 surrounding the distal portion of the pouch. The string may be held in position by feeding it through a sleeve (such as is the case with drawstring pants) or through spaced apart belt-loop type loops. The size of the distal orifice 124 is reduced by pulling on the free end 126 of the drawstring, causing it to cinch the pouch 120.

20

Cutting Tools

Another technique that may be used to increase the size of the distal orifice of a satiation pouch is to use a cutting tool to cut a larger opening into the pouch. If performed on a pouch located within the body, the tool is an endoscopic tool that is introduced through the esophagus and into pouch, preferably under visualization.

25

If the pouch is tapered towards its distal end, removing a section of the distal end will increase the orifice size. Figs. 16 through 19B show tools that may be used for this purpose.

30

Fig. 16 shows pouch 2 positioned within a stomach S. Endoscopic scissors 130 are passed through the esophagus and into the pouch 2, and are used to trim the distal end off of the pouch 2, thereby increasing the size of distal orifice 6. In any of the cutting tool

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embodiments, the pouch 2 may include markings 132 which indicate where cuts should be formed to achieve various orifice diameters.

Referring to Fig. 17, the distal end of the pouch 2 may be opened using an endoscopic electrode, such as a bi-polar or monopolar RF electrode wire 134 that may be energized and drawn across the pouch material to remove a portion of the pouch 2. A variety of electrode configurations may be used, including the "bow" configuration shown, a wire having a distal tip electrode, or a plurality of wires 134a configured in a basket-type arrangement as shown in Fig. 18. Such a basket-type arrangement may be expanded into contact with the pouch using a balloon 136. Alternatively, the wires may be shape-memory wires pre-formed to the expanded position and contained within a sheath until they are positioned within the pouch, and then released into their expanded position to perform the cutting operation.

Other forms of cutting-type tools may also be used to increase the distal orifice size on a satiation pouch. For example, the pouch may be incised with a laser directed onto the wall of the pouch, or using a jet of a chemical substance selected to dissolve a portion of the pouch but to also be well-tolerated by the gastric mucosa and the patient. In one embodiment, the pouch may be made of a material that is not affected by the chemical, with a distal cuff on the pouch that is readily dissolved by the chemical. Chemical is then directed on the cuff if it becomes necessary to increase the orifice size.

As yet another example, a cutting device similar to an aortic-punch used for cardio-vascular applications may be used to enlarge the distal orifice of a satiation pouch. Referring to Figs. 19A and 19B, punch device 138 includes a hollow elongate shaft 140 fluidly coupled to a suction port 142. A rod 144 extends through the shaft 140 and a punch tip 146 is carried by the rod 144. Sharp cutting edges 148 are formed along the proximal perimeter of the punch tip 146. An actuator 150 coupled to the rod 144 moves the punch tip 146 towards and away from the end of the shaft 140.

During use, the instrument is passed through the pouch such that the punch tip 146 extends out the distal orifice of the pouch. The shaft 140 is moved laterally to cause a portion of the pouch surrounding the distal orifice to be captured between the punch tip 146 and the perimeter of the shaft 140. The user manipulates the actuator 150 to draw the punch tip 146 in a proximal direction, causing the cutting edges 148 to slice through the captured portion of the pouch. Suction applied to the suction port 142 removes the

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removed fragments of the pouch from the operative site. The process is repeated until the distal orifice has been increased to the desired size.

It should be noted that, although these tools describe use of cutting tools to cut along the circumference of the pouch, a pouch might have its distal orifice size increased
5 by simply forming a longitudinal cut adjacent to its distal end.

Various embodiments of satiation devices and methods for expanding exit orifices have been described herein. These embodiments are given by way of example and are not intended to limit the scope of the present invention. It should be appreciated,
10 moreover, that the various features of the embodiments that have been described may be combined in various ways to produce numerous additional embodiments. Also, while various materials, dimensions, shapes, implantation locations, etc. have been described for use with disclosed embodiments, others besides those disclosed may be utilized without exceeding the scope of the invention. Lastly, while the pouches have been described for use in controlling feelings of hunger, the barrier devices described herein
15 may be equally suitable for use with other prosthetic devices positionable within the body, including prosthetic valves implanted in the lower esophagus or proximal stomach for controlling gastro-esophageal reflux disease (GERD).

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What is claimed is:

1. A method of positioning a prosthetic device within a patient having an esophagus, a stomach, and a gastro-esophageal junction region, the method comprising
5 the steps of:
 - providing a prosthetic device having a proximal opening and a central passage;
 - securing the prosthetic device at the gastro-esophageal junction region of the patient, with the prosthetic device oriented such that food ingested by the
10 patient passes from the esophagus into the proximal opening and through the central passage, and exits the prosthetic device through an exit orifice into the interior of the stomach; and
 - modifying the size of the exit orifice.
- 15 2. The method of claim 1 wherein the modifying step is performed after the securing step.
3. The method of claim 1 wherein the modifying step is performed prior to the securing step.
20
4. The method of claim 1 wherein:
 - the prosthetic device includes a pouch having a distal opening, and the method further provides a first component attachable to the pouch, the first component including a distal orifice having a size different than a size of the distal
25 opening;
 - the modifying step includes attaching the component to the pouch such that ingested food exiting the central passage flows through the distal orifice and into the stomach.
- 30 5. The method of claim 4, further including the step of replacing the first component with a second component, the second component having an second distal orifice having a size different from the size of the first distal orifice.

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6. The method of claim 4, further including the step of removing the component from the pouch to further modify the size of the exit orifice.

5 7. The method of claim 4 wherein the first component includes a flow restrictive insert positionable within the central passage of the pouch.

8. The method of claim 4 wherein the first component includes a flow restrictive device attachable to an exterior portion of the pouch.

10

9. The method of claim 1, wherein the prosthetic device includes a deformable member coupled to the prosthetic device, and wherein modifying step includes deforming the deformable member to modify the size of the exit orifice.

15 10. The method of claim 9 wherein the deformable member is formed of malleable material.

11. The method of claim 9 wherein the deformable member is formed of ductile material.

20

12. The method of claim 9 wherein the deformable member is formed of an inflatable chamber and the modifying step includes modifying the volume of inflation fluid within the inflatable chamber.

25 13. The method of claim 9 wherein the modifying step includes the step of extending a dilator through the central passage and expanding the dilator to expand the deformable member.

14. The method of claim 9 wherein the modifying step includes applying
30 compressive forces against the exterior of the prosthetic device to compact the deformable member.

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15. The method of claim 1 wherein the prosthetic device includes a longitudinal slit extending from the distal opening along a wall of the prosthetic device, and a zipper carriage engaged with wall sections adjacent the longitudinal slit and moveable in a proximal direction to increase the effective length of the slit and in a distal direction to decrease the effective length of the slit, the modifying step including the step of moving the zipper carriage.

16. The method of claim 1 wherein the prosthetic device includes a diaphragm extending at least partially across the central passage, the diaphragm including a shutter defining the distal opening and being rotatable between expanded and contracted positions to increase and decrease the effective diameter of the distal opening, wherein the modifying step includes rotating the shutter.

17. The method of claim 1 wherein the providing step provides a cord forming a loop around at least a portion of the prosthetic device, and wherein the modifying step includes adjusting the effective diameter of the loop.

18. The method of claim 1 wherein the modifying step includes removing a portion of the prosthetic device adjacent to the distal opening.

19. The method of claim 18 wherein the removing step includes cutting the prosthetic device using an energized electrode.

20. The method of claim 18 wherein the removing step includes cutting the prosthetic device using a sharpened tool.

21. The method of claim 18 wherein the removing step includes cutting the prosthetic device using a laser.

22. The method of claim 18 wherein the removing step includes cutting the prosthetic device using a chemical stream.

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23. A medical device positionable within a gastro-esophageal junction region of a patient having an esophagus and a stomach, the medical device comprising:

5 a prosthetic device having a proximal opening, an exit orifice, and an central passage between the proximal opening and exit orifice, a proximal portion of the prosthetic device positionable within the gastro-esophageal junction region such that the proximal opening is in substantial alignment with the esophagus; and
a flow restrictive component on a distal portion of the prosthetic device, the flow restrictive component moveable between a first position in which the exit orifice has a first size and a second position in which the exit orifice has a second
10 size that is smaller than the first size.

24. The medical device of claim 23 wherein in the first position the flow restrictive component is detached from to the prosthetic device and wherein in the second position the flow restrictive component is attached to the prosthetic device.

15

25. The medical device of claim 24 wherein the flow restrictive component is attachable to a distal portion of the prosthetic device.

26. The medical device of claim 24 wherein the flow restrictive component is
20 an insert positionable within the central passage.

27. The medical device of claim 23 wherein the flow restrictive component is a deformable member, wherein the first position is a compressed position and the second position is an expanded position.

25

28. The medical device of claim 27 wherein the deformable member is formed of malleable material.

29. The medical device of claim 27 wherein the deformable member is formed
30 of ductile material.

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30. The medical device of claim 27 wherein the deformable member is formed of an inflatable chamber.

31. The medical device of claim 23 wherein the flow restrictive component
5 includes a diaphragm extending at least partially across the central passage, the diaphragm including a shutter defining the distal opening and being rotatable between expanded and contracted positions to increase and decrease the effective diameter of the distal opening.

10 32. The medical device of claim 23 wherein the flow restrictive component includes a cord forming a loop around at least a portion of the prosthetic device, the loop adjustable to a tightened position to compress the prosthetic device.

33. A method of treating obesity, comprising the steps of:
15 providing a prosthetic device having a proximal opening and a central passage;
securing the prosthetic device at the gastro-esophageal junction region of the patient, with the prosthetic device oriented such that food ingested by the patient passes from the esophagus into the proximal opening;
20 causing food ingested by the patient to pass from the esophagus into the proximal opening and through the central passage, and to exit the prosthetic device through an exit orifice into the interior of the stomach; and
modifying the size of the exit orifice.

25 34. The method of claim 33 wherein the modifying step is performed after the securing step.

35. The method of claim 34 wherein:
prior to the modifying step food ingested by the patient flows through the
30 exit orifice at a first rate; and
following the modifying step food ingested by the patient flows through the exit orifice at a second rate different than the first rate.

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36. The method of claim 35 wherein the first rate is faster than the second rate.

37. The method of claim 35 wherein the first rate is slower than the second
5 rate.

38. The method of claim 33 wherein the modifying step is performed prior to
the securing step.

10 39. The method of claim 33 wherein:
the prosthetic device includes a pouch having a distal opening, and the
method further provides a first component attachable to the pouch, the first
component including a distal orifice having a size different than a size of the distal
opening;
15 the modifying step includes attaching the component to the pouch such
that ingested food exiting the central passage flows through the distal orifice and
into the stomach.

40. The method of claim 39, further including the step of replacing the first
20 component with a second component, the second component having an second distal
orifice having a size different from the size of the first distal orifice.

41. The method of claim 39, further including the step of removing the
component from the pouch to further modify the size of the exit orifice.
25

42. The method of claim 39 wherein the first component includes a flow
restrictive insert positionable within the central passage of the pouch.

43. The method of claim 39 wherein the first component includes a flow
30 restrictive device attachable to an exterior portion of the pouch.

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44. The method of claim 33, wherein the prosthetic device includes a deformable member coupled to the prosthetic device, and wherein modifying step includes deforming the deformable member to modify the size of the exit orifice.

5 45. The method of claim 44 wherein the deformable member is formed of malleable material.

46. The method of claim 44 wherein the deformable member is formed of ductile material.

10

47. The method of claim 44 wherein the deformable member is formed of an inflatable chamber and the modifying step includes modifying the volume of inflation fluid within the inflatable chamber.

15 48. The method of claim 44 wherein the modifying step includes the step of extending a dilator through the central passage and expanding the dilator to expand the deformable member.

49. The method of claim 44 wherein the modifying step includes applying
20 compressive forces against the exterior of the prosthetic device to compact the deformable member.

50. The method of claim 33 wherein the prosthetic device includes a longitudinal slit extending from the distal opening along a wall of the prosthetic device,
25 and a zipper carriage engaged with wall sections adjacent the longitudinal slit and moveable in a proximal direction to increase the effective length of the slit and in a distal direction to decrease the effective length of the slit, the modifying step including the step of moving the zipper carriage.

30 51. The method of claim 33 wherein the prosthetic device includes a diaphragm extending at least partially across the central passage, the diaphragm including a shutter defining the distal opening and being rotatable between expanded and contracted

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positions to increase and decrease the effective diameter of the distal opening, wherein the modifying step includes rotating the shutter.

52. The method of claim 33 wherein the providing step provides a cord
5 forming a loop around at least a portion of the prosthetic device, and wherein the modifying step includes adjusting the effective diameter of the loop.

53. The method of claim 33 wherein the modifying step includes removing a
10 portion of the prosthetic device adjacent to the distal opening.

54. The method of claim 53 wherein the removing step includes cutting the
prosthetic device using an energized electrode.

55. The method of claim 53 wherein the removing step includes cutting the
15 prosthetic device using a sharpened tool.

56. The method of claim 53 wherein the removing step includes cutting the
prosthetic device using a laser.

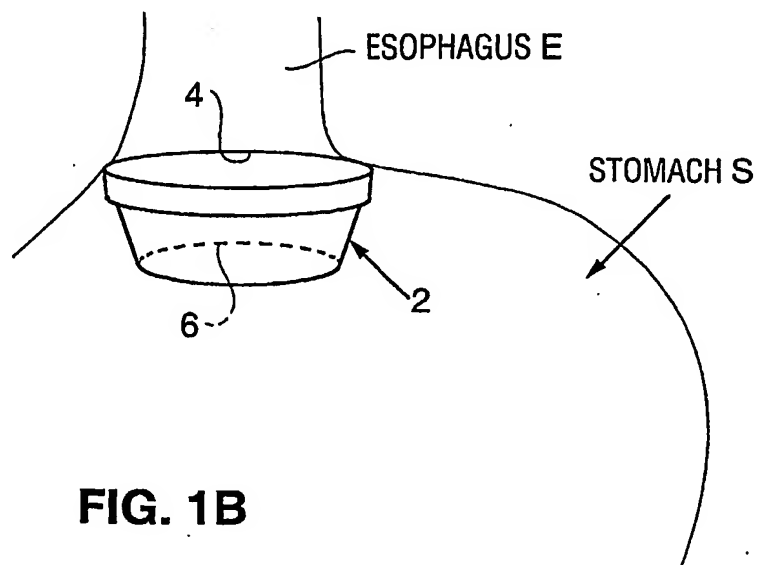
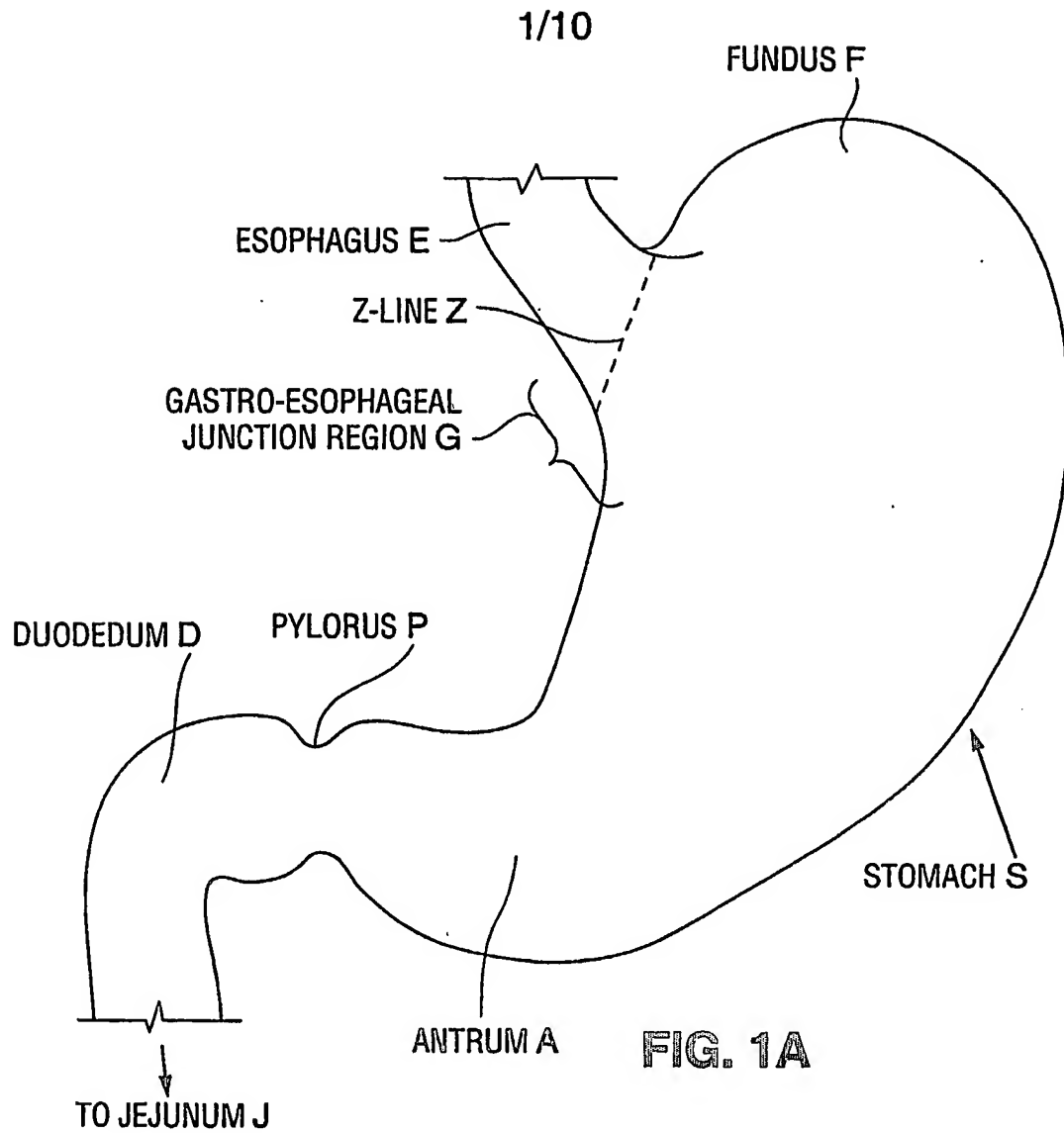
57. The method of claim 53 wherein the removing step includes cutting the
20 prosthetic device using a chemical stream.

58. A method of treating obesity, comprising the steps of:
providing a base device and a prosthetic device having a proximal opening
25 and a central passage;
securing the base device at the gastro-esophageal junction region of the
patient;
allowing tissue of the gastro-esophageal junction region to at least partially
heal for a period of time following the securing step;
30 after the allowing step, attaching the prosthetic device to the base device,
with the prosthetic device oriented such that food ingested by the patient passes
into the proximal opening;

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causing food ingested by the patient to pass into the proximal opening and through the central passage, and to exit the prosthetic device through an exit orifice into the interior of the stomach.

- 5 59. The method of claim 58 wherein the period of time is at least one day.
60. The method of claim 58 wherein the period of time is more than one week.
61. The method of claim 58, wherein the proximal opening is larger than the
10 exit orifice.
62. The method of claim 58 further including the step of modifying the size of
 the exit orifice.
63. The method of claim 62 wherein the modifying step is performed after the
15 step of attaching the prosthetic device to the base device.
64. The method of claim 62 wherein:
 prior to the modifying step food ingested by the patient flows through the
 exit orifice at a first rate; and
20 following the modifying step food ingested by the patient flows through
 the exit orifice at a second rate different than the first rate.
65. The method of claim 64 wherein the first rate is faster than the second rate.
- 25 66. The method of claim 64 wherein the first rate is slower than the second rate.



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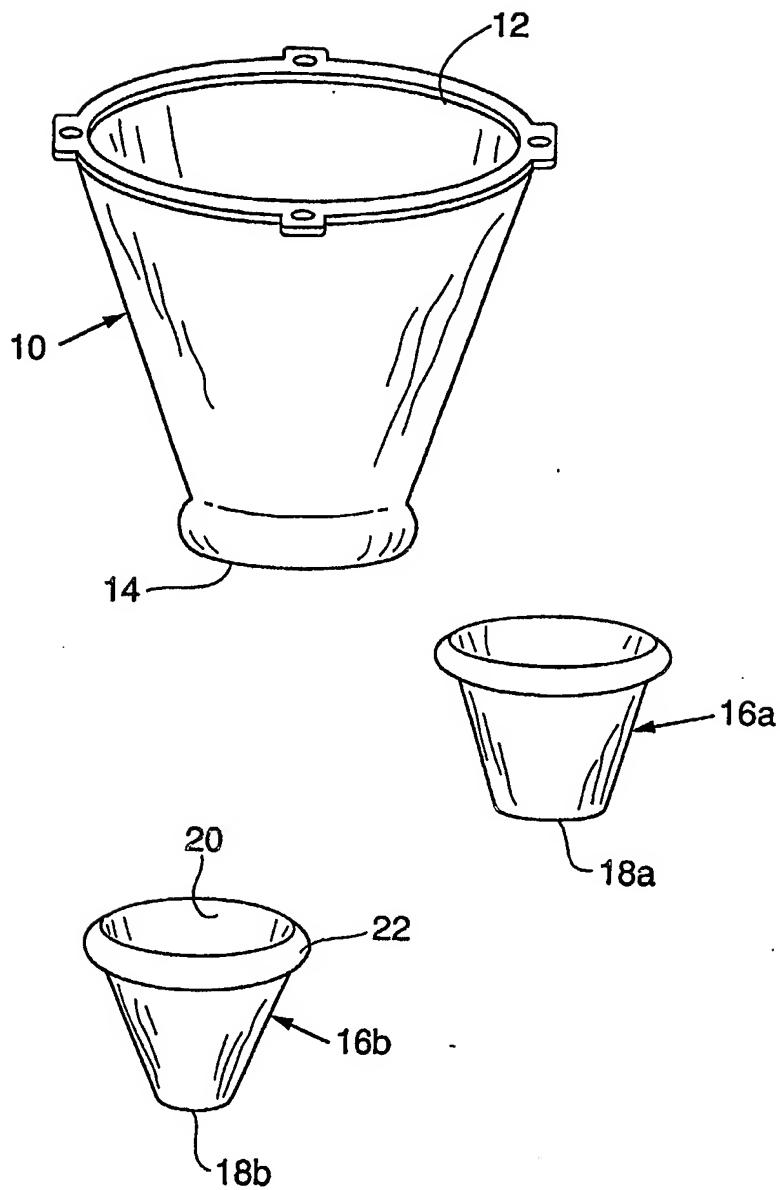


FIG. 2A

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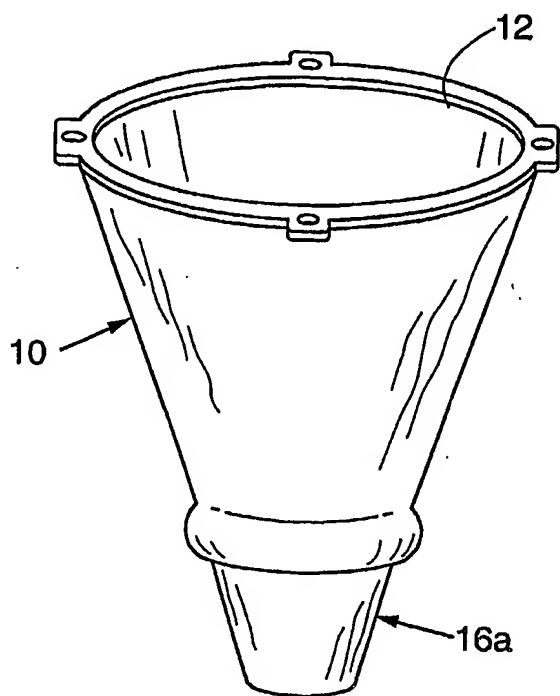


FIG. 2B

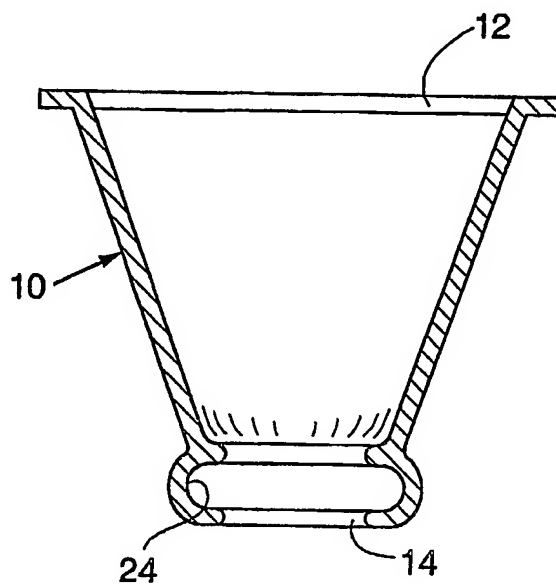


FIG. 3A

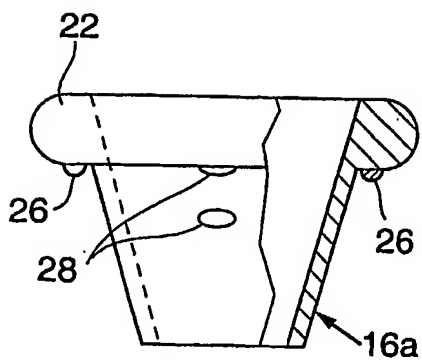


FIG. 3B

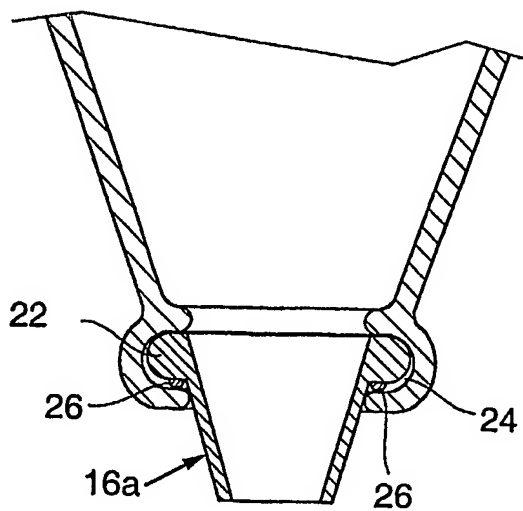
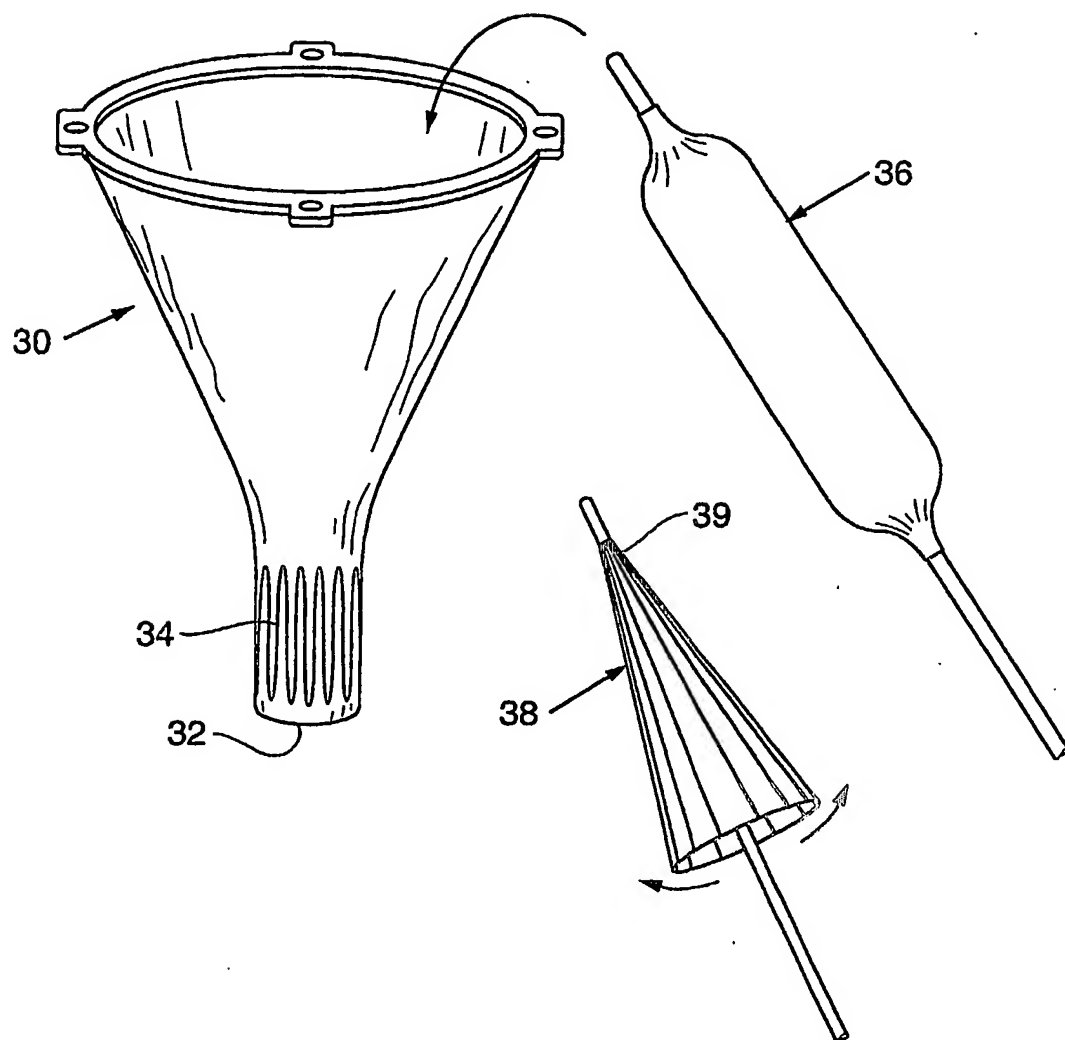


FIG. 3C

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**FIG. 4A**

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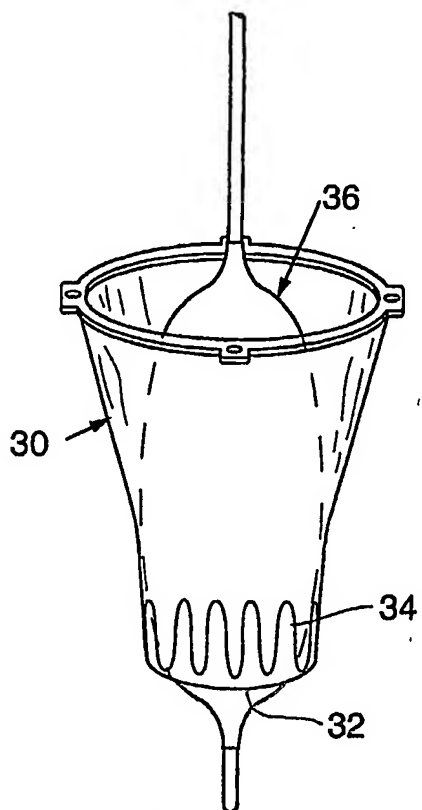


FIG. 4B

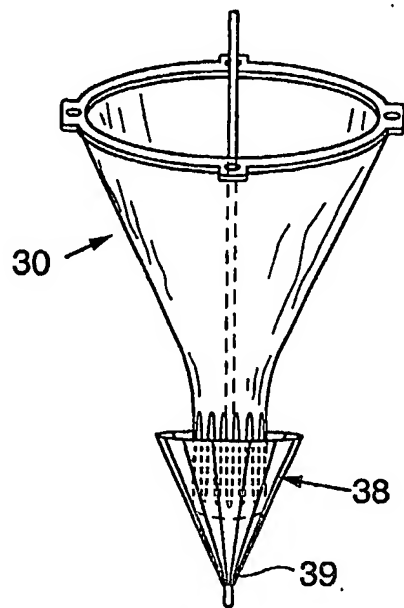


FIG. 4C

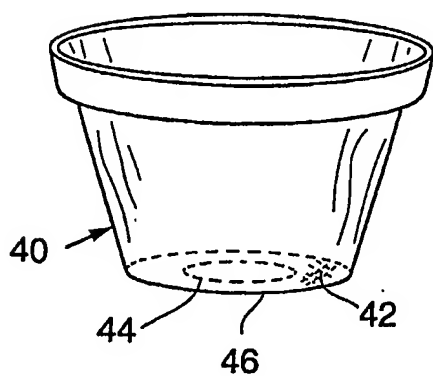


FIG. 5A

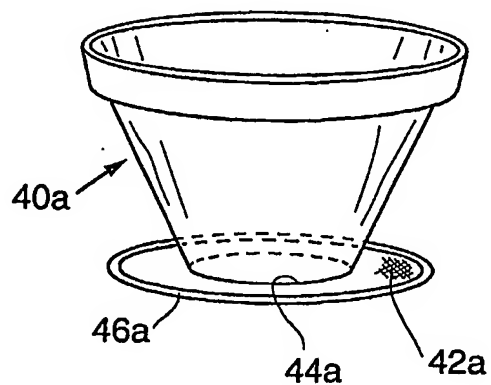


FIG. 5B

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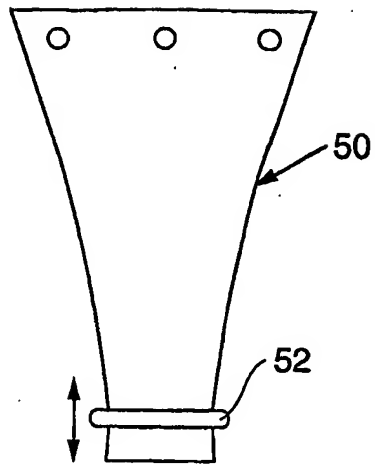


FIG. 6A

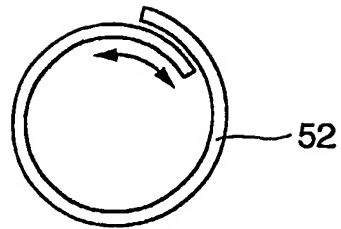


FIG. 6B

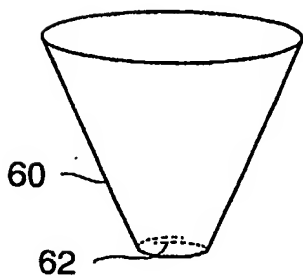
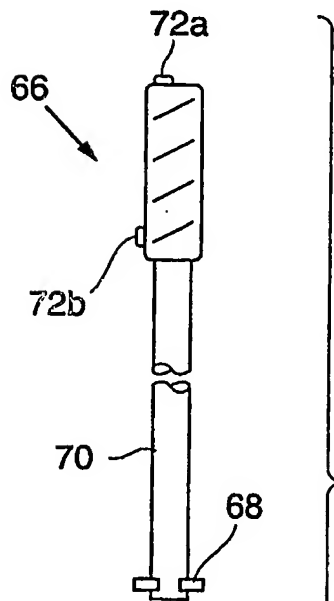


FIG. 7

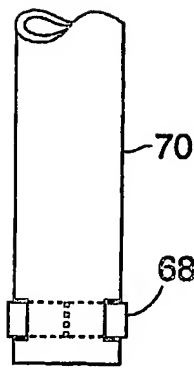


FIG. 8A

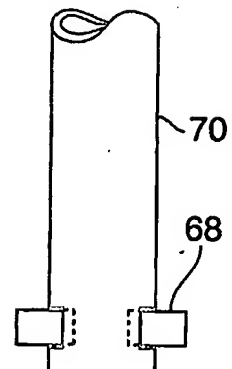


FIG. 8B

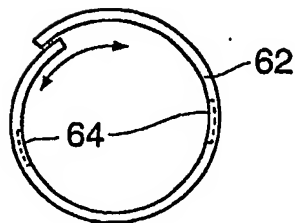


FIG. 9A

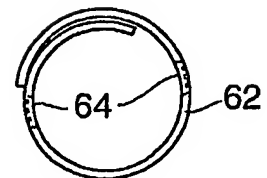
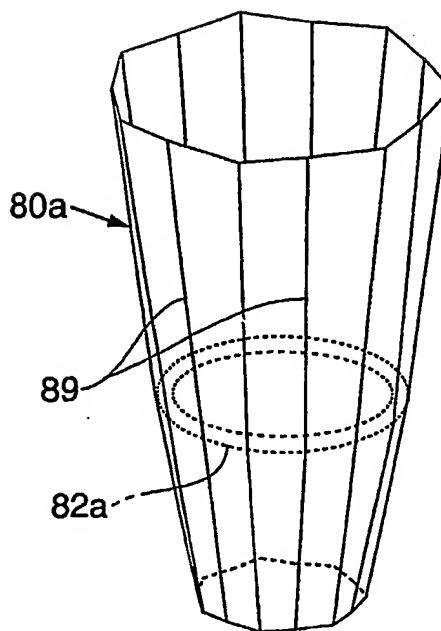
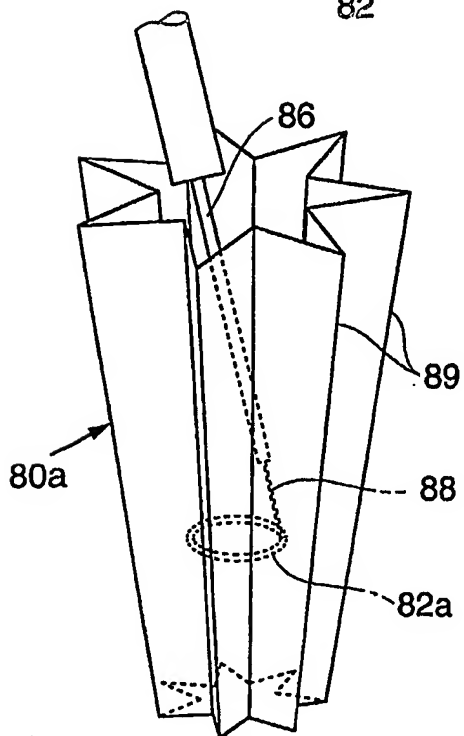
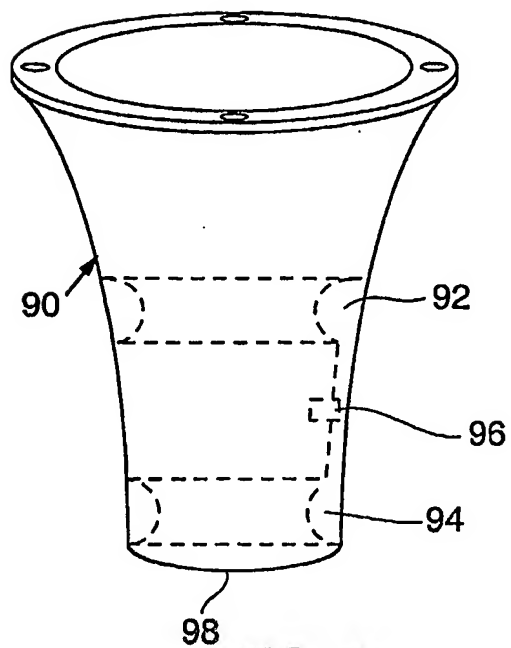
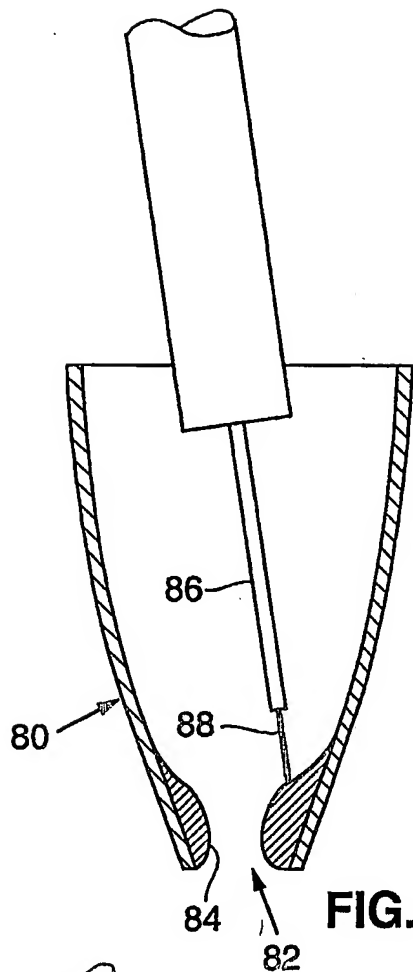


FIG. 9B

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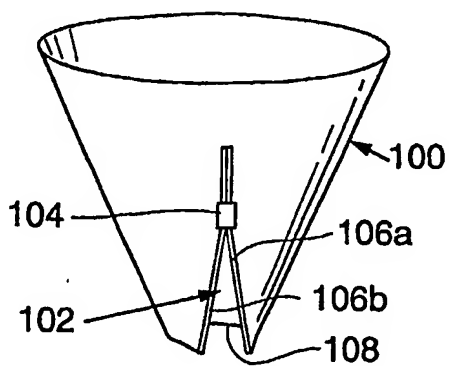


FIG. 13

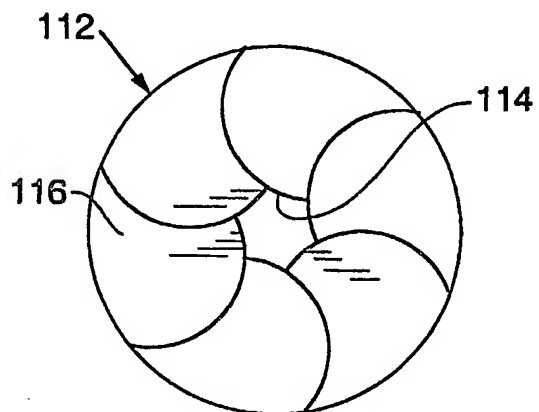


FIG. 14A

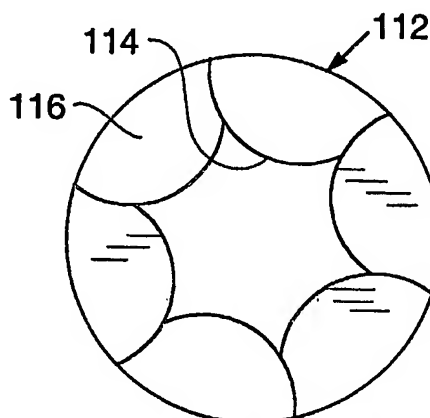


FIG. 14B

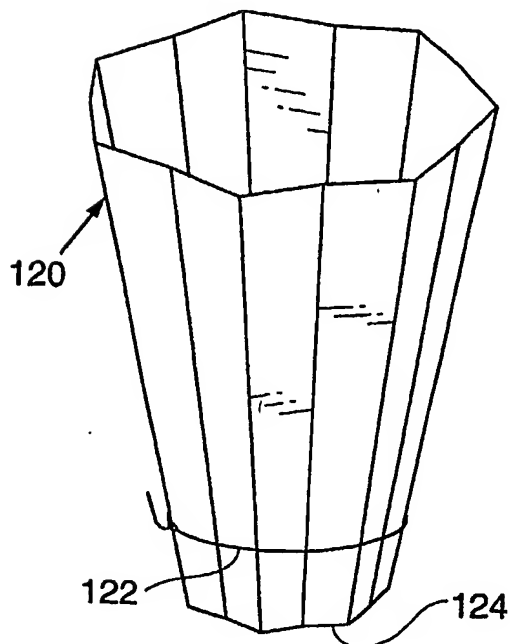


FIG. 15A

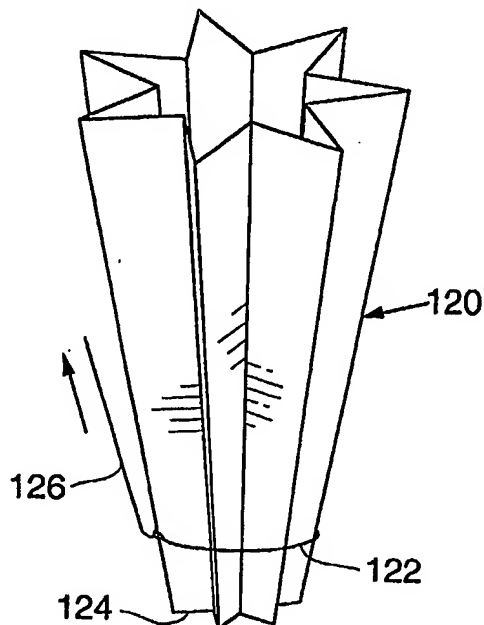
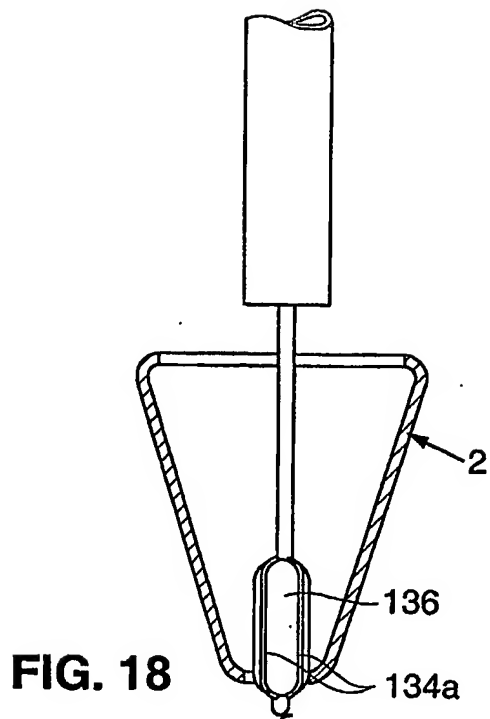
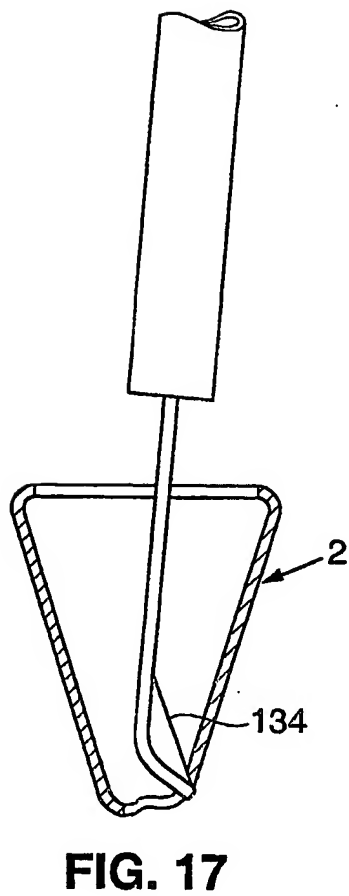
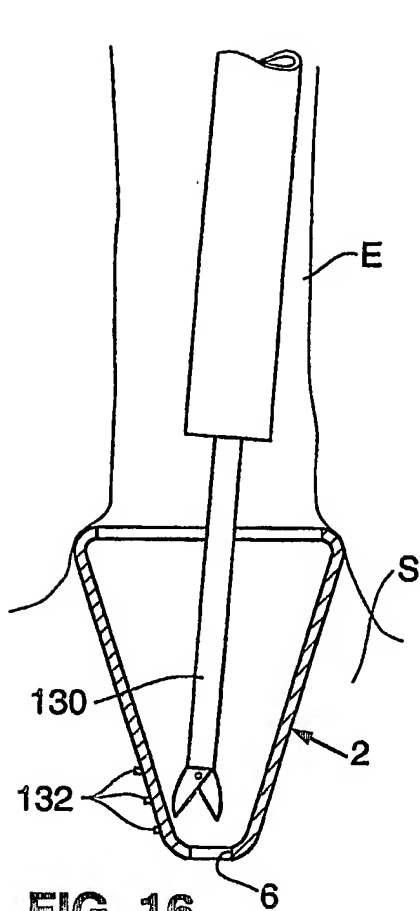


FIG. 15B

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